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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jean-Luc Clement

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04/13/2009

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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

PAPER NUMBER

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MAIL DATE

DELIVERY MODE

04/13/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,203	Applicant(s) CLEMENT ET AL.	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1-18 are objected to because of the following informalities: Claim 1 recites "at top" and "distalmost." Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 20 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 1, applicant positively recites part of a human, i.e. ""via the anchoring members, to the vertebrae". Thus claims 1-7 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim 10 is rejected under 35 U.S.C. § 101 because they appear to embrace more than one statutory class of invention. Claims which are intended to embrace both product or machine and process is precluded by language of 35 USC 101, which sets forth statutory classes of the invention in the alternative only. Claim 1 as amended appears to be directed to the apparatus, however claim 10 appears to recite a method of manufacturing the device, and thus appears to be directed to a process. As such,

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claim 20 appears to embrace multiple statutory classes of invention which is prohibited (See *Ex parte Lyell*, 17 USPQ2d 1548 (1990)).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

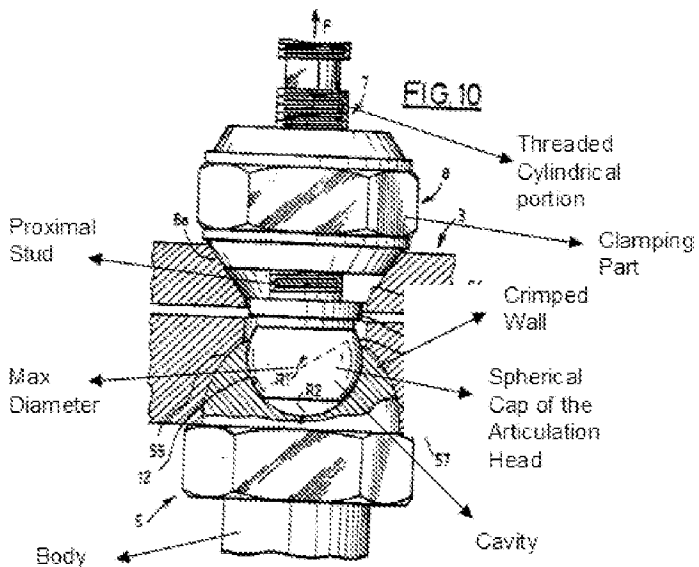
5. Claim 10 is invalid under 35 USC 112, second paragraph, since a claim which purports to be both machine and process is ambiguous and therefore does not particularly point out and distinctly claim the subject matter of the invention. *Ex parte Lyell*, 17 USPQ2d 1548 (1990). Claim 10 will be treated as a product by process claim as explained below. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by- process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (See MPEP 21102.02). If the applicant intends to claim a method of manufacture, the applicant should do so, rewriting claim 10 in independent form. In such a case, a separate 103 rejection is also made below to expedite prosecution.

Claim Rejections - 35 USC § 102

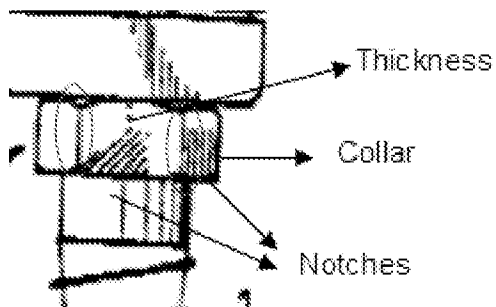
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1-2, 4-11, 13-16, 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al US 6,267,765.

Regarding **Claim 1**, Taylor discloses a vertebral osteosynthesis equipment comprising an anchoring member with a proximal stud and body (see Fig below) with threads (#4), where the proximal stud articulates with respect to the body (see Col 5 lines 5-7), the proximal stud comprises an articulation head with a spherical cap, a threaded cylindrical portion extending from a top of the cap (as seen in Fig below), where a maximum diameter of the cap is at the distal most end (see Fig below as indicated by the dashed line), the body comprises a crimped wall defining a cavity surrounding the cap with an at least partially hemispherical external proximal form (as seen in Fig below), a linking rod (#2), connecting parts (#3), and clamping part (see Fig below).

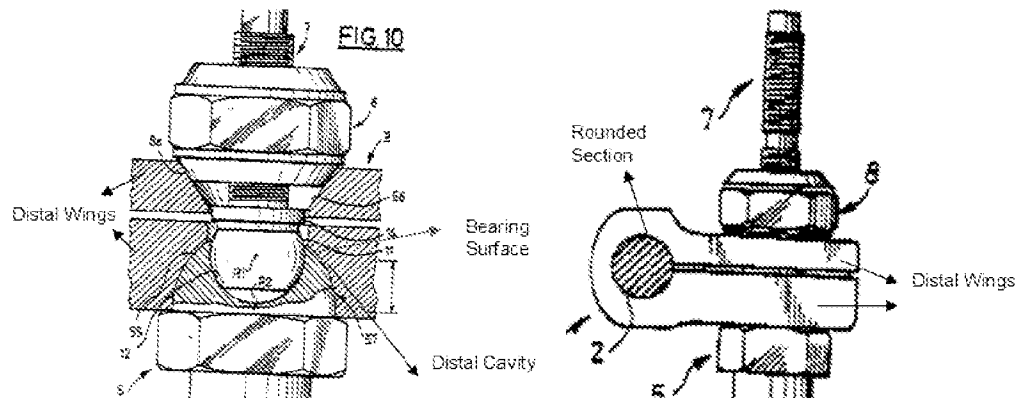


Regarding **Claim 2**, Taylor discloses a proximal gripping portion comprising a collar with a plural of radial notches extending through an entire thickness of the collar (as seen in Fig below, where the notches are circled).

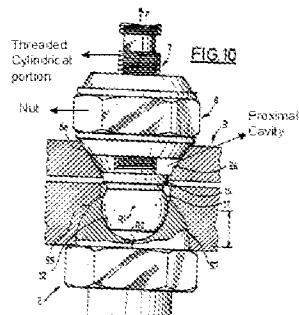


Regarding **Claim 4**, Taylor discloses the connecting part has a rounded section, two parallel distal wings, a distal cavity with a greater diameter than the crimped wall which rests against the crimped wall (as seen in Fig below).

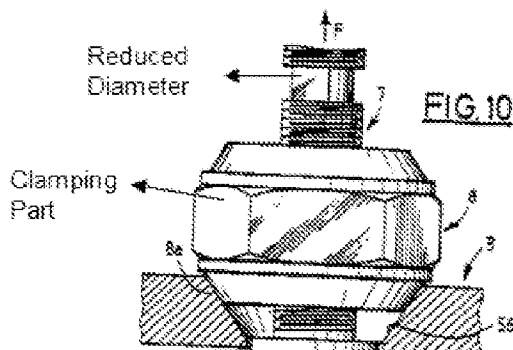
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Regarding **Claims 5-6**, Taylor discloses the clamping part/nut engages the threaded cylindrical portion and is seated in a proximal cavity of the proximal branch of the connecting part, wherein the proximal cavity and nut are conical in shape (as seen in fig below).



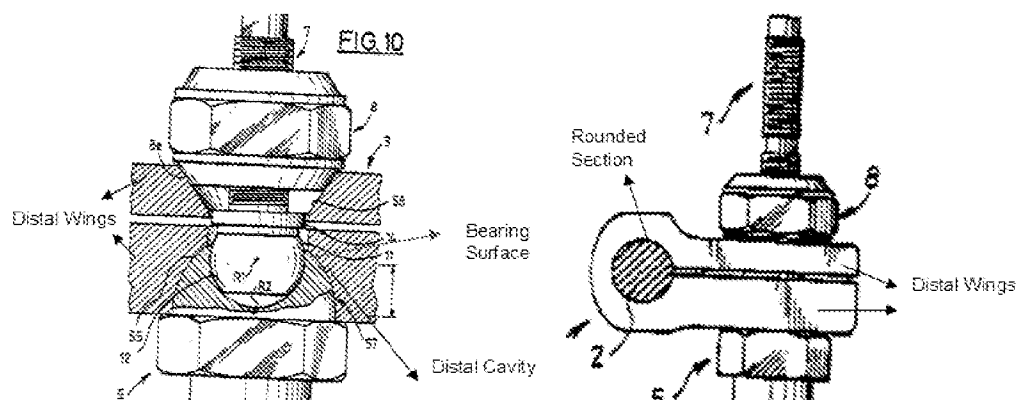
Regarding **Claims 7, 15, 14**, Taylor discloses the stud exhibits a zone of reduced diameter capable of breaking off (as seen in Fig below and see Col 5 lines 54-60).



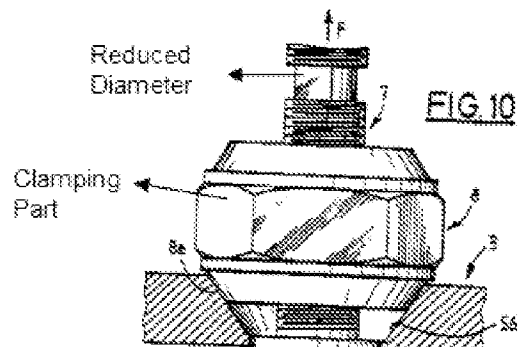
Regarding **Claims 8-9**, Taylor discloses the proximal stud and connecting part have means (#13, #15 respectfully) to immobilize the proximal stud in rotation with the connecting part (see Col 5 lines 8-20), wherein the means comprises at least one flat surface on the threaded cylindrical portion and at least one corresponding flat surface on the connecting part (see Figs 1-2, 10, Col 5 lines 8-20, where #13 and #15 have corresponding flat surfaces).

Regarding **Claim 10**, Taylor discloses that the crimped wall is at least partially hemispherical around the articulation head (see Fig above).

Regarding **Claim 11**, Taylor discloses the connecting part has a rounded section, two parallel distal wings, a distal cavity with a greater diameter than the crimped wall which rests against the crimped wall (as seen in Fig below).



Regarding **Claim 13**, Taylor discloses the stud exhibits a zone of reduced diameter at a location above the clamping part (as seen in Fig below).

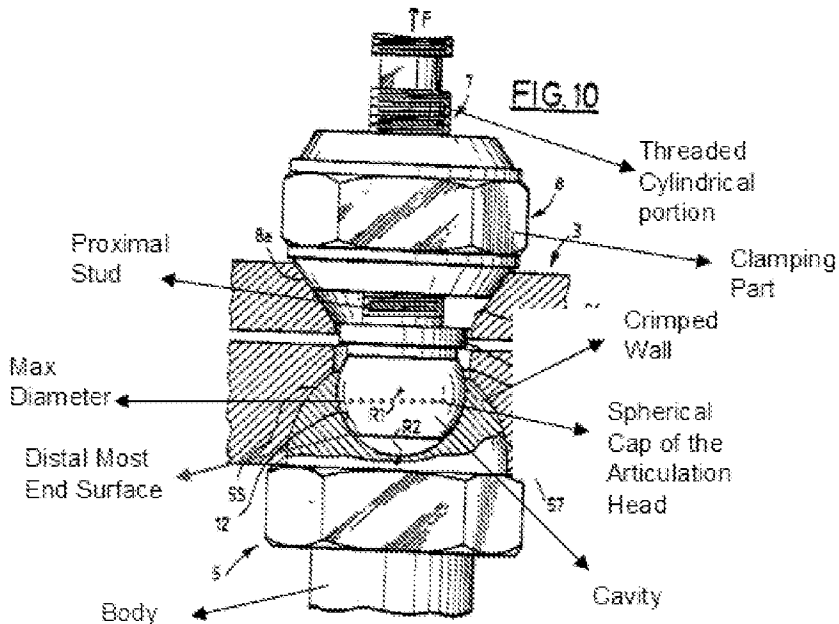


Regarding **Claims 16, 18**, Taylor discloses the proximal stud and connecting part have means (#13, #15 respectfully) to immobilize the proximal stud in rotation with the connecting part (see Col 5 lines 8-20).

Regarding **Claim 19**, Taylor discloses a vertebral osteosynthesis equipment comprising an anchoring member with a proximal stud and body (see Fig below) with threads (#4), where the proximal stud articulates with respect to the body (see Col 5 lines 5-7) the proximal stud comprises an articulation head with a spherical cap, a threaded cylindrical portion extending from a top of the cap (as seen in Fig below), the body comprises a crimped wall defining a cavity surrounding the cap with an at least partially hemispherical external proximal form (as seen in Fig below), where the largest diameter of the cavity defining a surface facing the distal most end surface of the spherical cap (see Fig below and see Col 5 lines 5-7, where the cap can articulate

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within the cavity, where when the most distal end surface can be directed to and facing the largest diameter of the cavity), a linking rod (#2), connecting parts (#3), and clamping part (see Fig below).



Claim Rejections - 35 USC § 103

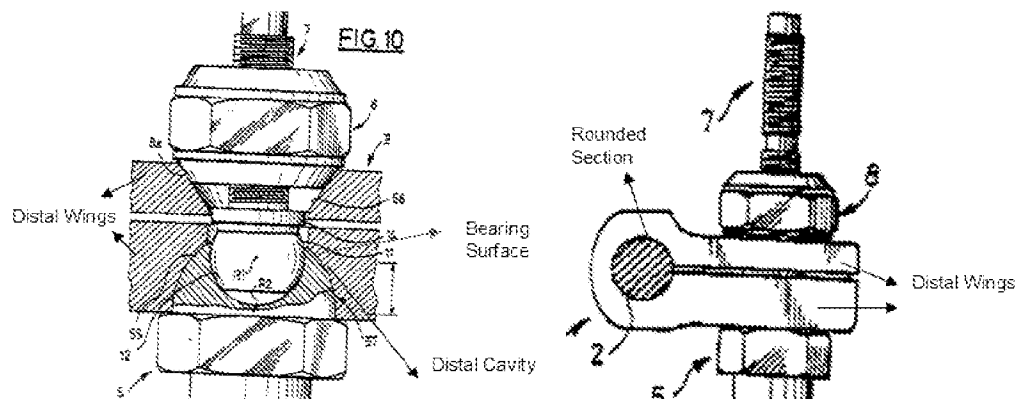
8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. **Claims 3, 12, 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765.

Taylor et al discloses the claimed invention as discussed above with a collar (see Claim 2 and Figs above and see abstract and Col 4 lines 64-67, where the collar is used for gripping, where the collar cooperates with a tool #6). Taylor also teaches the

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connecting part has a rounded section, two parallel distal wings, a distal cavity with a greater diameter than the crimped wall which rests against the crimped wall (as seen in Fig below) and the proximal stud and connecting part have means (#13, #15 respectfully) to immobilize the proximal stud in rotation with the connecting part (see Col 5 lines 8-20).



Taylor et al does not specifically disclose four notches at 90 degrees to one another.

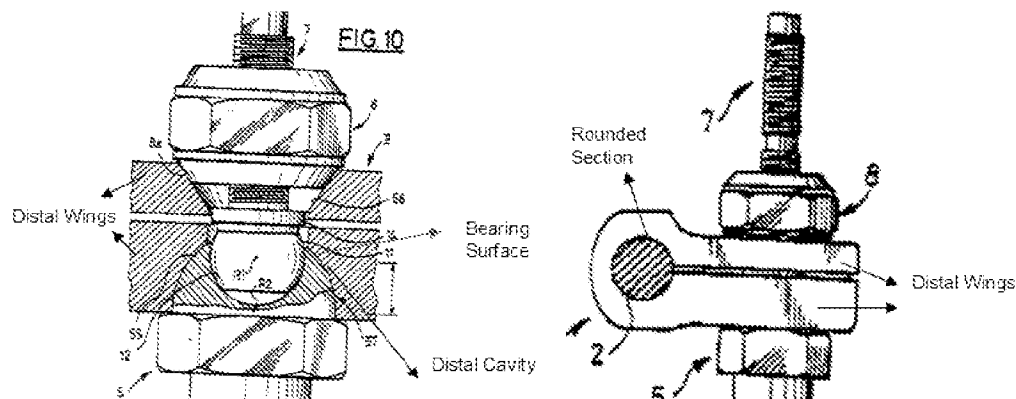
It would have been obvious to one having ordinary skill in the art at the time the invention was made to have four notches at 90 degrees to one another since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

10. **Claims 3, 12, 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765.

Taylor et al discloses the claimed invention as discussed above with a collar (see Claim 2 and Figs above and see abstract and Col 4 lines 64-67, where the collar is used for gripping, where the collar cooperates with a tool #6). Taylor also teaches the

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connecting part has a rounded section, two parallel distal wings, a distal cavity with a greater diameter than the crimped wall which rests against the crimped wall (as seen in Fig below) and the proximal stud and connecting part have means (#13, #15 respectfully) to immobilize the proximal stud in rotation with the connecting part (see Col 5 lines 8-20).



Taylor et al does not specifically disclose four notches at 90 degrees to one another.

However, Stone et al discloses multiple tools with a socket having four corresponding notches at 90 degrees to match with corresponding four notches of an anchor (as seen in Figs 4, 5, 7-7a).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the collar of Taylor et al to have four notches at 90 degrees to each other as taught by Stone et al so that the collar of Taylor et al can cooperate with a tool having a corresponding female cavity to the notches, wherein the notches are a simple substitution of one known element for another to obtain

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predictable results for a tool/driver to grip a bone anchor/fastener/screw (see Figs 4, 5, 7-7a and abstract and see Col 2 lines 16-25).

11. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765 in view of Maughan US 6,082,923.

Taylor discloses a method for manufacturing the anchoring member by providing the articulation head with a spherical cap (#11), a cavity surrounded by a wall (as seen in Fig 10), which is hemispherical, where the articulation head engages the cavity but does not specifically disclose crimping a wall around said articulation head.

However, Maughan teaches a similar anchoring member with an articulation head (#28) engaging a cavity (#64), where the head engages the socket and the walls of the socket crimp the head (as seen in Figs 2, 5-6 and see Col 4 lines 6-20) and exhibits a partially hemispherical form.

It would have been obvious to modify the walls of the cavity of Taylor to crimp it over the articulating head as taught by Maughan because it applies a known technique to a known device/method ready for improvement to yield predictable results of retaining and articulating head in a cavity (see Col 4 lines 6-20).

12. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765.

Taylor et al discloses the claimed invention as discussed above with a collar (see Claim 2 and Figs above and see abstract and Col 4 lines 64-67, where the collar is used

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for gripping, where the collar cooperates with a tool #6) but does not specifically disclose four notches at 90 degrees to one another.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have four notches at 90 degrees to one another since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

13. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765 in view of Rudd et al US 5,645,565.

Taylor et al discloses the claimed invention as discussed above with a collar (see Claim 2 and Figs above and see abstract and Col 4 lines 64-67, where the collar is used for gripping) but does not specifically disclose four notches at 90 degrees to one another.

However, Rudd discloses a collar with four notches at 90 degrees from one another (as seen in Figs 2-2a, 4, where there are four notches at 90 degrees from one another).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the collar of Taylor et al to have four notches at 90 degrees to each other as taught by Rudd because it is a simple substitution of known type of gripping surface for another to obtain predictable results of gripping a medical fastener (see Figs 2-2a, 4 and Col 3 lines 21-35).

14. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al US 6,267,765 in view of Wenstrom et al US 6,045,573.

Taylor et al discloses the claimed invention as discussed above with a collar (see Claim 2 and Figs above and see abstract and Col 4 lines 64-67, where the collar is used for gripping, where the collar cooperates with a tool #6) but does not specifically disclose four notches at 90 degrees to one another.

However, Wenstrom discloses a collar with four notches at 90 degrees from one another (#110 as seen in Fig 2).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the collar of Taylor et al to have four notches at 90 degrees to each other as taught by Wenstrom because it applies a known technique to a known device ready for improvement to yield predictable results of gripping a bone fastener (see Fig 2 and Col 3 lines 44-67).

Response to Arguments

15. Applicant's arguments with respect to claims above have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733